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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,958	05/31/2006	Kai Michael Exner	12810-00257-US	9216
23416 7590 09/12/2007 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899			EXAMINER CUTLIFF, YATE KAI RENE	
			ART UNIT 1621	PAPER NUMBER
			MAIL DATE 09/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/580,958	EXNER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Yate' K. Cutliff	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/31/2006 &amp; 07/26/2006</u> .                             | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Priority*

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "in the presence of," in line 2 of claim 2 and line 8 of claim 5 renders the scope indefinite.
4. Claims 7 and 8 recites the limitation "methyl sulfate is from 0.1 to 5%" in line 4 of claim 7 and line 2 of claim 8, renders the scope indefinite because Applicant has not clearly defined what the proportion percentage relates to.
5. Claim 9 recites the limitation "where ammonia is employed" in line 2. There is insufficient antecedent basis for this limitation in the claim 1.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1- 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surmatis, ('485) in view of Schleich et al. ('281).

### **Applicant Claims**

Applicant claims a process for preparing vitamin A acetate of formula (I) by reaction beta-vinylionol of formula (II) with triphenylphosphine in the presence of sulfuric acid to give C15 salt of the formula (III) with the salt being hydrogen sulfate and/or methylsulfate. Subsequent to the preparation of the C15 salt, the C15 salt is reacted with C5 acetate of formula (IV) in a Wittig reaction in water as solvent and I the

presence of a base. The synthesis of C15 salt of formula (III) starts with the beta-vinylionol in a solvent **consisting of** methanol, water and aliphatic, cyclic or aromatic hydrocarbons having 5 to 8 carbon atoms.

Rejected claim 2 discloses a reaction temperature for the Wittig reaction and the equivalent range for ammonia within the reaction process. Rejected claim 3 discloses the reaction temperature for the synthesis of C15 salt of formula (III). Rejected claims 4 and 6 disclose the concentration range for the acid in the synthesis of C15 salt of formula (III). Rejected claims 5 and 12 discloses further range limitation for the solvent used in the synthesis of C15 and discloses that the organic component of the solvent is heptane, with claim 5 disclosing another temperature range for the synthesis of C15. Rejected claim 7 discloses that a C15 mixture is used in the Wittig reaction to produce the compound of formula (I). Rejected claim 8 discloses an amount of methyl sulfate in the C15 salt. Rejected claim 9 discloses that the ammonia in the Wittig reaction is in aqueous solution. Rejected claim 10 discloses that the process is a continuous process. Rejected claim 11 discloses that the solvent composition can be returned to the process after synthesis of the C15. Rejected claim 13 discloses the purity of the triphenylphosphine. Rejected claims 14 and 15 disclose the percentage of beta-vinylionol and triphenylphosphine present in the reaction process for producing C15 salt.

#### **Determination of the Scope and Content of the Prior Art (MPEP §2141.01)**

Surmatis teaches the process for making the Wittig salt (phosphonium salt) of an alpha, beta-unsaturated alcohol by treating the alcohol of formula II ('485) with

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phosphine of formula I ('485) in the presence of a salt of a weak organic base with a strong acid in an inert organic solvent. (see column 4, lines 48-53). Further, the preferred conventional inert organic solvents which from the reaction medium are solvents ..., such as lower alkanols, e.g., methanol, ethanol, the aromatic hydrocarbons, e.g., benzene... (see column 4, lines 63 – 67). Strong acids are disclosed to be, inorganic acids, e.g. ...  $\text{H}_2\text{SO}_4$ ... (see column 4, line 45). Surmatis teaches that the reaction, temperature and pressure are not critical, and any temperature between 0°C and the reflux temperature of reaction mixture can be suitably utilized, preferably about 20°C to 30°C. (see column 5, lines 4-8) Further, it is disclosed that the ratio of reactants is not critical. Preferably, from 1 to 10 moles of the alpha, beta-unsaturated alcohol of formula II and 1 to 10 moles of the phosphine of formula I are utilized in the presence of 1 to 10 moles of the salt of the weak organic base with a strong acid. It is particularly preferred that about equal molar part of the phosphine, alcohol and salt be utilized. (see column 5, lines 9 – 16).

**Ascertainment of the Difference Between the Scope of the Prior Art  
and the Claims (MPEP §2141.012), & Obviousness Rational and Motivation  
(MPEP §2142-2143)**

Surmatis lacks the express teaching of: (i) the Wittig reaction using C5 acetate of formula (IV) in water as solvent in the presence of a base, (ii) the base is ammonia, (iii) the base in aqueous solution, (iv) the reaction being semi-continuously or continuously, and (v) optionally returning the solvent, used in the synthesis of C15, to the process.

With regard to (i) above, Schleich et al. discloses a process wherein the Wittig reaction involves the use of  $\gamma$ -acetoxytiglic aldehyde (C5 Acetate) in the vitamin A acetate process. (see column 1, line 14 – 15). Further, water is used as a solvent. (see column 1, line 22). Additionally, it is stated that the presence of a base is required in the reaction. (see column 1, lines 43 – 45).

With regard to (ii) above, Schleich et al. teaches that one of the bases that may be used is ammonia. (see column 1, lines 47 – 51).

With regard to (iii) above, Schleich et al., as stated above teaches that water and an ammonia base is in the reaction therefore it can be presumed that an aqueous solution exist.

With regard to (iv) above, Schleich et al. states that the present reaction can be carried out either batch-wise or continuously. (see column 2, lines 1-2). The Examiner notes that semi-continuous is between a batch-wise and continuous reaction.

With regard to (v) above, the Examiner states that this step is well within the purview of an ordinary artisan.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made by Applicant to combine the teachings of Surmatis and Schleich et al. to produce a process for preparing vitamin A acetate with increased efficiency.

With regard to the multitude of ranges for solvent mixtures used in the synthesis of the C15 salt of formula (III), based on the above prior art references, any one of which appear to be one of several obvious possibilities. It is the Examiner's position

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that the specified range of percent methanol, water and aliphatic, cyclic or aromatic hydrocarbons having 5 to 8 carbon atoms of the solvent solution is a results effective variable because changing the range would clearly affect the yield of the C15 salt. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art to choose this range in order to obtain the desired end result.

### ***Double Patenting***

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).



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11. Claims 1, 5 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 - 14 of copending Application No. 10/582,912 in view of Surmatis ('485).

This is a provisional obviousness-type double patenting rejection.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the process of taught by the instance claims are embraced by the claims of the copending application ('582) and is an obvious variant of the reaction of copending application ('582). The secondary reference of Surmatis teaches a similar process for making the phosphonium salt. Specifically, Surmatis teaches the use of an unsaturated alcohol in a reaction with a tri phenylphosphine in the presence of an acid is a solvent mixture. The discussion of Surmatis as set out in paragraph 9 above is incorporated herein by reference.

12. Additional references listed on Form 892 consider but not cited by the Examiner are consider pertinent to the state of the art of Applicant's invention.

13. **No claims are allowed.**

**Conclusion**

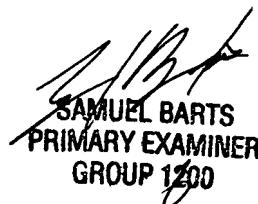
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yate' K. Cutliff whose telephone number is (571) 272-9067. The examiner can normally be reached on M-TH 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571) 272 - 0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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